Foreign Trade Association of Southern California
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April 1, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Attention: Docket No. 02N-0278

Re: Comments on the Bio-terrorism Act of 2002, Title III; Subtitle A, Section 305 (Registration) and Section 307 (Prior Notice)

Dear Sir or Madam:

The Foreign Trade Association of Southern California (FTA) thanks the Food and Drug Administration for the opportunity to participate in the public comment period relating to FDA's plans for implementing the Public Health Security and Bio-terrorism Preparedness and Response Act of 2002 (the Bio-terrorism Act). The FTA is a private, non-profit trade association that represents over 250 members of the local international trade community. Founded in 1919, the FTA is the oldest organization promoting the growth of international trade in the Southern California area. It acts as an informational resource and network center for its members, and monitors and advocates legislative issues at the local, state and federal levels. In this post-September 11th environment, FTA supports the federal government's efforts to secure our borders while fostering a legitimate trade and travel-friendly environment. We agree with Secretary Ridge's statement that economic security equates with national security, a philosophy we see as potentially undermined by FDA's proposed regulations.

As it relates to the Bio-terrorism Act and FDA's proposed rules, the FTA is primarily concerned with legislative language relating to the importation of food across our land borders and registration of importing agents, thus our comments here will be limited to sections 307 and 305.

Section 307, Prior Notice

In the proposed regulations, FDA requires that importers or purchasers of food notify FDA of their importation by noon the day prior to the food's arrival at the U.S. port of entry. In responding to this proposal, FTA comments as follows:

?? With the exception of the exact arrival time, all of the information mandated by FDA is currently available when the entry is transmitted at time of importation. Congress seems to have misunderstood FDA's powers regarding the importation

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of foodstuffs. As it stands now, no imported foodstuff is allowed into the stream of commerce until it is authorized for distribution by the FDA. By making the import process so much more complicated, it encourages those who wish us harm to conceal the true nature of their importations by not identifying them as foodstuff but as something else. We prefer not to lay out in detail ideas which "bad guys" might rely upon. Suffice it to say a terrorist need only corrupt an existing shipper or carrier of manufactured goods and rely on his existing good record as a means to evade these new requirements!

?? Given the current limitations of staffing, it will be impossible for FDA to thoroughly review (conduct risk management on) the 20,000 daily submissions it expects to receive without a sophisticated computer system and the experiences of the FAA, IRS and Customs make clear it is impossible for a federal agency to build a computer system of the sort needed in the time allowed. FDA would be better served to work closely with Customs to identify risk factors and arrange for Customs to include those risk factors in its pre-arrival shipment profiling currently underway. Except for arrival information, we understand FDA already receives all the information it needs into OASIS from ABI, but is unable to receive arrival information from Customs AMS system. We contend FDA would be better served to spend the $4.4 million it estimates the new computer system will cost to work out a link between AMS and OASIS to close the loop of needed information.

?? If indeed data must be transmitted prior to arrival, then instead of creating a new computer system and a requirement for duplicate transmission of data into a new system with lacks checks or edits, it makes more sense (economically and practically) for FDA to require transmission of entry information prior to arrival (we withhold comment as to the amount of time until later). If indeed there is a question whether such action by FDA would compromise the Customs requirements regarding entry pre-filing, then coordination between the agencies is in order, rather than a costly and likely unworkable system being newly created.

?? As currently proposed, the Prior Notice computer system will have no edits or checks. It will simply accept whatever data is transmitted. The old adage of GIGO comes to mind and leads inevitably to the likelihood that FDA will spend massive amounts of time trying to reconcile what it has been given as part of the pre-arrival process with what is in OASIS. Frankly, such efforts will seriously compromise the agencies ability to properly screen incoming goods. It is already horribly short-staffed and cannot keep up with the current flow of information and goods. The regulation as proposed will undermine the agencies' efforts even more.

?? Further FTA views with some concern ambiguity surrounding the ability of importers to issue updates and amendments to their notices to FDA of an arriving food shipment. In the sphere of international trade, the importer and exporter always anticipate changes and we recommend FDA maintain appropriate

flexibility as well. One change in each category is simply unrealistic. For example, the Fresh Produce Association has pointed out a number of legitimate reasons a change in pre-notification might be needed. We would add another. It is quite common for there to be equipment failures coupled with changes in plans. It is the norm for larger companies to have arrangements/contracts with specific trucking operations. However, when there is a greater quantity of cargo to move than that operation can handle on a given day, independent owner-operators will be hired. The need for that service is generally not known by the day before importation, much less by noon the day before. Further, it is not unheard of for a truck to breakdown while en route. As currently written, something as simple as the mechanical failure of a truck would require that load to sit an additional day because the way the regulations are currently written, a change in carrier is not considered either an update or an amendment. As a side note, we question why FDA even needs to know the identity of the carrier. We can find no language in the Act which authorizes such information as a data element. In fact, requiring it simply duplicates Customs' own requirements and, frankly, Customs is in a much better position to evaluate risk as relates to carriers. It currently does so and already has in place programs which distinguish between secure carriers (such as the Land Border Carrier Initiative) and others.

?? Paramount in FDA's approach to issuing regulations in order to comply with the Bio-terrorism Act is the critical need for FDA and the various federal inspectional agencies to coordinate their efforts.

The recent establishment of the Department of Homeland Security absorbed some agencies posted at our ports of entry, while leaving others untouched. In the need to keep our borders and supply chain secure, FTA recommends that FDA consult and coordinate with Customs as that agency works through its own experience with proposed prior notice rules. As you may know, U.S. Customs recently concluded a public comment period regarding the advance submittal of manifest information for shipments bound for a U.S. port of entry. In addition, Customs has worked closely with industry to find rules and procedures which are workable following its attempt to unilaterally impose rules in the ocean context which have all but brought trade to a halt. At the Port of Los Angeles/Long Beach alone, a container used to move once every 11 seconds, 24/7! Because of the "24 hour rule," what used to take hours is now taking 5 to 7 days to move. Does FDA really want to find itself the cause of such a catastrophe when it comes to the nation's food supply? The longer the food sits, the more likely it is to rot!

?? FDA is proposing that the importer provide advance notice on noon the day prior to arrival. Customs, on the other hand, sought to receive advance manifest notification four hours prior to arrival for trucks, twenty-four hours for vessels and eight to ten hours for air shipments. These contrasting timeframes underscore the need for the agencies to coordinate their efforts and present a consistent and workable process to trade and industry.

?? We are concerned that in its laudable effort to secure the U.S. food supply, FDA has failed to focus on extracting accurate information from the import community, and instead has focused on a seemingly arbitrary timeframe for prior notice.

We commented above how the lack of edits/checks in the propose Prior Notice computer system will likely lead to conflicting information with that in OASIS and how the agency will drown under the attempt to reconcile those discrepancies.

In addition, we suggest that FDA consider development of a program that creates an incentive for reliable importers who operate in a secure environment and adhere to certain parameters set forth by FDA, Customs or any of the other agencies dealing with security. A similar program established by U.S. Customs, the Customs-Trade Partnership Against Terrorism (C-TPAT), could serve as a model. The idea behind C-TPAT is that if one makes the effort to have a secure supply chain, there should be rewards. While Customs maintains the right to and does examine all sorts of containers, including those imported by C-TPAT members, if a C-TPAT member's cargo is examined, it is given priority to the head of the line. Something similar should be included as part of FDA's risk management approach. Further, when FDA enacts such a program, we encourage the agency to make the program's incentives available to importers both large and small.

?? Additionally, regardless of whether we are discussing manufactured dry goods or foodstuffs, today's international trade operates in a just-in-time (JIT) environment, where, in an effort to keep overhead and expenses low, production corresponds as closely as possible with demand.

Recognition of JIT is critical when dealing with perishable goods. The maxim that cargo at rest is cargo at risk takes on even greater importance when dealing with items whose shelf life will be significantly reduced if delayed at the U.S. border. Decreased shelf life leads to increased prices, which in today's economy, is undesirable for all of us. Equally important, decreased shelf life leaves fertile situations for bacteria and other contaminants to grow while the cargo sits at produce sheds or on the side of the road waiting to cross.

In enacting these regulations, for them to be a success, FDA must give realistic consideration to the way in which companies operate. If the amount of time cargo is going to be held by truckers and others increases, then their risk for loss or damage increases. Hence, cost goes up and they will be forced to build larger holding facilities. If the risk for loss or damage increases, so does the risk for compromise of the foodstuff. Similarly, these newly built larger facilities also become targets of opportunity, whether for terrorists, bandits, drug lords, or other criminals.

?? Another area of concern for us is the amendments and updates. Allowing only one of each is simply unrealistic. By way of example, we note that changes in quantity require an amendment. For those products subject to USDA clearance, it is often necessary to unload those goods and then reload them. Trucks carrying fruits and vegetables often gas up to make sure they can make it to their next destination. Given that each state has its own weight limits, the amount of a given fruit or vegetable that can be loaded on a given truck changes with the weight of the truck. Therefore, when these items are loaded at locations near the border, one cannot anticipate what will go on which truck or in what quantity until appropriate weights and balances are considered. As a result, by allowing only one amendment and requiring that it be transmitted no later than two hours prior to arrival, FDA mandates that recently loaded trucks sit by the side of the road waiting for the FDA prior notice period to expire. By so doing, not only does FDA put the load at risk, it also contributes to contaminating the environment as the particulates from the truck spoil the air.

   A similar problem exists with updates to arrival information. While it is true that many ocean carriers now post arrival information on their websites, that data is subject to change. For example, a steamship line may anticipate that its vessel will arrive at noon on a given day. However, it may turn out in the last minute, the pier is overloaded and needs additional time so the vessel will be held at anchor. If so, the arrival time does not change. However, if the delay is known far enough in advance, the ship may slow its voyage and so stay on the sea longer. That information may not be known in time to meet the required two-hour window. Similarly, by air, one assumes a plane will land on time. What happens if LAS or SFO are fogged in or there is snow on the East Coast – and the closure of the airport is not known until the next morning? Such information at that late date is outside the two-hour window.

?? Finally, we take exception to FDA's conclusion that the American importer always knows what he is receiving and so transmission of data the day before is realistic. While it may be true that prepared and preserved items are clearly identified at time of order placement, that same maxim does not hold when dealing with fresh items, such as fruits, vegetables, fish, etc. Most of these shipments are shipped on a consignment basis to a U.S. based third party who acts as the agent of the exporter in selling them in the U.S. marketplace. Therefore, they do not know what they are getting until it arrives at their door. Harvesting can be the subject of delays caused by weather as well. Further, in the case of fish freshly caught, no one really knows the details of the catch until it is off-loaded and weighed and at that point is ready for movement. None of these events can be predicted by noon the day prior to shipment.

Section 305, Registration

While our primary concerns relating to the rulemaking process surrounding the Bio-terrorism Act center on the prior notice proposals, FTA does take some interest in Section 305 as it relates to registration provisions.

In its proposal, FDA seeks to make whoever transmits information to the agency to be responsible for the accuracy of that information. While FTA appreciates FDA's efforts to affix responsibility for data transmittal, it is unrealistic for ultimate responsibility to rest with a U.S. agent who may have received unreliable information from a foreign supplier which, even with the exercise of due diligence, cannot be identified in advance as unreliable. After all, the U.S. agent is just that: an agent. He is only as good as the information provided by his principal. Therefore, we view FDA's position as questionable under the basics of principal-agency law. We think that so long as the agent does not self-blind (fail to identify obviously unreliable information) and does accurately report the data he is given, he should be found to have discharged his obligations. Our position comports with the regulatory and statutory position taken by the Customs Service for years.

Finally, FTA views the October 17, 2003 deadline for implementation of this system as overly ambitious. We encourage FDA to have a backup system in place that does not involve manual review of all submission and will still allow compliance with the Bio-terrorism Act should the agency be unable to get the Prior Notice system fully operational in time. Trade-industry experience with the development of systems such as ACE (Automated Commercial Environment) and the maintenance of declining systems such as ACS (Automated Commercial System) suggests that endeavors such as the one proposed by FDA can be extremely time and labor intensive and simply do not work properly from the outset. What will FDA do if the system does not operate as anticipated?

Once again, the FTA appreciates the opportunity to work with FDA in keeping the U.S. food supply secure while expediting the flow of legitimate commerce. Our organization offers its years of collective knowledge of cross-border affairs as FDA addresses these important issues.

Very truly yours,

Barry E. Powell

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President